

selected from the group consisting of imipramine, amitriptyline, trimipramine, doxepin, desipramine, nortriptyline, protriptyline, amoxapine, clomipramine, maprotiline, and carbamazepine and bupropion, sertraline, fluoxetine, trazodone, and their pharmacologically effective esters and salts.

Kindly cancel claims 26-30 without prejudice or disclaimer thereof.

REMARKS

Upon entry of the foregoing amendment, claims 1-25 remain pending.

Initially, the Examiner is thanked for the very courteous and helpful interview of August 30, 2002 where Applicant's invention was discussed. While no agreement on the issues was reached, Applicant offers the following remarks which are believed to be consistent with the discussion during the interview.

By the present amendment, Claim 21 has been amended to correct a typographical error in the word "pharmaceutical" appearing in line 5 of the claim. A clean copy of the claim also appears in Appendix I attached hereto. In addition, claims 26-30 have been cancelled. Since the foregoing amendment reduces the number of issues on appeal without raising any new issues requiring further consideration and/or search, entry is proper.

In light of the cancellation of claims 26-30, Applicant respectfully request withdrawal of the 35 U.S.C. § 112 rejection presented in paragraphs 5-6 of the action.

The only remaining rejection is that of claims 8-25 under 35 U.S.C. § 251 based upon an allegedly defective reissue oath/declaration. This rejection is, once again, respectfully traversed.

As discussed during the interview, Applicant directs the Examiner's attention to MPEP Section 1449.02, which reads in pertinent part:

In appropriate circumstances, a reissue application may be placed into interference with a patent or pending application. A patentee may provoke an interference with a patent or pending application by filing a reissue application, if the reissue application includes an appropriate reissue error as required by 35 U.S.C. 251. Reissue error must be based upon applicant error; a reissue cannot be based solely on the error of the Office for failing to declare an interference or to suggest copying claim for the purpose of establishing an interference. See *In re Keil*, 808 F.2d 830, 1 USP2d 1427 (Fed. Cir. 1987); *In re Dien*, 680 F.2d 151, 214 USPQ 10 (CCPA 1982); *In re Bostwick*, 102 F.2d 886, 888, 41 USPQ 279, 281

(CCPA 1939); and *In re Guastavino*, 83 F.2d 913, 916, 29 USPQ 532, 535 (CCPA 1936). See also *Slip Track Systems, Inc. v. Metal Lite, Inc.*, 159 F.3d 1337, 48 USPQ2d 1055 (Fed. Cir. 1998) (Two patents issued claiming the same patentable subject matter, and the patentee with the earlier filing date requested reexamination of the patent with the later filing date (Slip Track's patent). A stay of litigation in a priority on invention suit under 35 U.S.C. 291, pending the outcome of the reexamination, was reversed. The suit under 35 U.S.C. 291 was the only option available to Slip Track to determine priority of invention. Slip Track could not file a reissue application solely to provoke an interference proceeding before the PTO because it did not assert that there was any error as required by 35 U.S.C. 251 in the patent.). **A reissue application can be employed to provoke an interference if the reissue application:**

- (A) **adds copied claims which are not present in the original application;**
- (B) **amends claims to correspond to those of the patent or application with which an interference is sought; or**
- (C) contains at least one error (not directed to provoking an interference) appropriate for the reissue.

In the first two situations, the reissue oath/declaration must assert that applicant erred in failing to include claims of the proper scope to provoke an interference in the original patent application. (Emphasis added)

The reissue oath/declaration filed by Applicant specifically states that the error was "[t]he failure to include claims of proper scope to provoke an interference in the original patent application." Thus, the "error" is consistent with the language appearing in MPEP Section 1449.02. Accordingly, the declaration is proper and withdrawal of the rejection is in order.

Applicant once again requests that an interference be declared between the present reissue application and U.S. Patent 5,958,962. The proposed count and corresponding claims are the same as that presented in Section II on pages 7-8 of the preliminary amendment filed herein (with the exception that now cancelled claims 26-30 would no longer be included among the claims corresponding to the proposed count).

Applicants are also attaching Appendix II to this response, which appendix provides a side-by-side comparison of claims in the '962 patent with claims in this reissue application. This appendix further evidences that the claims in question relate to the "same patentable invention" and thus, an interference is in order.

Finally, in paragraph 8 of the outstanding action, the Examiner states that "an interference will only be declared if all claims have been determined to be allowable." Applicant submits that such is not the appropriate standard to apply. Attention is directed to MPEP Section 2306 which reads in pertinent part:

An interference may be declared between an application and a patent if the application and patent are claiming the same patentable invention, as defined in 37 CFR 1.601(n), and **at least one of the applicant's claims** to that invention are patentable to the applicant. (Emphasis added)

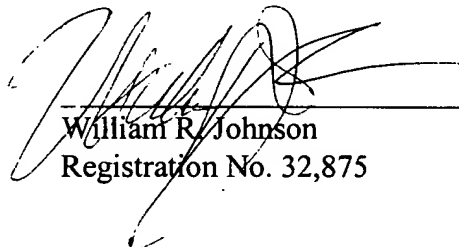
Thus, only **one** of Applicant's claims need to be patentable for an interference to be declared. The outstanding action indicates that Claims 1-7 are patentable. Accordingly, Applicant respectfully requests that an interference be immediately declared.

As a final matter should the Examiner have any questions regarding this amendment or the application in general, he is invited to telephone the undersigned at his earliest convenience.

No additional fees are believed to be due, however, the Commissioner is hereby authorized to charge the amount to Deposit Account No. 14-0629.

Respectfully submitted,

NEEDLE & ROSENBERG, P.C.

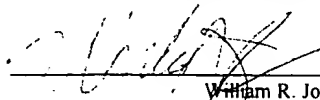


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William R. Johnson

6.3.04

Date



ATTORNEY DOCKET NO. 14127.0001U1

SERIAL NO. 09/672,843

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APPENDIX I

SEP 12 2002

TECH CENTER 1600/29

21. (Amended) A drug combination comprising an effective pharmaceutical amount of an opioid antagonist selected from the group consisting of nalmefene, naltrexone, nalmefene, nalorphine, nalbuphine, thebaine, levallorphan, oxymorphone, butorphanol, buprenorphine, levorphanol, meptazinol, pentazocine, dezocine, and their pharmacologically effective esters and salts, and an effective pharmaceutical amount of an antidepressant, which antidepressant is selected from the group consisting of imipramine, amitriptyline, trimipramine, doxepin, desipramine, nortriptyline, protriptyline, amoxapine, clomipramine, maprotiline, and carbamazepine and bupropion, sertraline, fluoxetine, trazodone, and their pharmacologically effective esters and salts.

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Appendix II

SEP 12 2002

Dante Serial No. 09/672,843	U.S. Patent No. 5,958,962 TECH CENTER 1600/2900
8. A method of treating depression in a patient who is also being treated for alcoholism comprising	1. A method of treating alcoholism and alcohol dependence comprising
administering to a patient an effective amount of an opioid antagonist selected from the group consisting of nalmefene, naltrexone, nalmefene, nalorphine, nalbuphine, thebaine, levallorphan, oxymorphone, butorphanol, buprenorphine, levorphanol, meptazinol, pentazocine, dezocine, and their pharmacologically effective esters and salts, and	administering to a mammal naltrexone where the effective dose is a molar equivalent weight between 5 and 15 mg and
Also: 9. The method according to claim 8 wherein the opioid antagonist is naltrexone administered in an amount of from 10 to 150 mg.	
an effective amount of an antidepressant, which antidepressant is selected from the group consisting of imipramine, amitriptyline, trimipramine, doxepin, desipramine, nortriptyline, protriptyline, amoxapine, clomipramine, maprotiline, and carbamazepine and bupropion, sertraline, fluoxetine, trazodone, and their pharmacologically effective esters and salts	fluoxetine where the effective dose is a molar equivalent weight between 5 and 15 mg.
Also: 12. The method according to claim 9 wherein fluoxetine is administered in a dosage of between 10 and 40 mg.	

<p>21. A drug combination comprising</p> <p>an effective pharmaceutical amount of an opioid antagoist selected from the group consisting of nalmefene, naltrexone, nalmefene, nalorphine, nalbuphine, thebaine, levallorphan, oxymorphone, butorphanol, buprenorphine, levorphanol, meptazinol, pentazocine, dezocine, and their pharmacologically, effective esters and salts,</p> <hr/> <p>Also:</p> <p>22. The drug combination according to claim 21 wherein an opioid antagonist is naltrexone present in an amount of 10-150 mg.</p>	<p>2. A pharmaceutical composition comprising</p> <p>naltrexone where the pharmacologically effective dose is a molar equivalent weight between 5 and 15 mg and</p>
<p>and an effective pharmaceutical amount of an antidepressant, which antidepressant is selected from the group consisting of imipramine, amitriptyline, trimipramine, doxepin, desipramine, nortriptyline, protriptyline, amoxapine, clomipramine, maprotiline, and carbamazepine and bupropion, sertraline, fluoxetine, trazodone, and their pharmacologically effective esters and salts.</p> <hr/> <p>Also:</p> <p>23. The drug combination according to claim 22 wherein the antidepressant is fluoxetine present in the amount of 20-80 mg.</p> <p>24. The drug combination according to claim 22 wherein the antidepressant is fluoxetine present in more than one dosage, each dosage having an amount of 10-40 mg.</p>	<p>fluoxetine where the pharmacologically effective dose is a molar equivalent weight between 5 and 16 mg.</p>